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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,672	10/10/2000	Yasir Skeiky	014058-009041US	2671

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,672

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-27, 105-109 and 111-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4, 7, 12, 15, 18, 20-27 is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5, 6, 8, 11, 13, 14, 16, 17, 19, 105-109 and 111-115 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.
2. Applicants' submission filed on 19March2004 has been entered. Claims 9 and 110 have been cancelled. Claims 1, 4, 7, 10, 12, 15, 18, 22, 25, 27, 105, 107, 109, 111, 112, and 114 have been amended.
3. Applicants' Amendment, received 14June2004, is acknowledged. Claim 10 is canceled. Claims 4 and 18 have been amended.
4. Claims 1-8, 11-27, 105-109, and 111-115 are pending and under consideration.

Rejections Moot/Withdrawn

5. The rejection of claims 9 and 110 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic fragments or fusion products of immunogenic fragments, is moot in light of the proposed cancellation of the claims.
6. The rejection of claims 1-8, 11-27, 105-109, and 111-115 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic fragments or fusion products of immunogenic fragments, is withdrawn in light of the proposed amendments of the claims.

Claim Objections

7. Claim 11 is objected to because the claim depends from a canceled claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-3 and 105-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the difference between the set of claims 2-3 and the set of claims 105-106.

Claims 2 and 3 are drawn to a composition wherein antigens MTb81 from *M. tuberculosis* and Mo2 antigen from *M. tuberculosis* are linked forming a fusion polypeptide which has the amino acid sequence of TbF14.

Claims 105 and 106 are drawn to a fusion protein comprising an MTb81 antigen from *M. tuberculosis* and an Mo2 antigen from *M. tuberculosis* wherein said fusion polypeptide has the amino acid sequence of TbF14.

11. Claims 5-6 and 107-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the difference between the set of claims 5-6 and the set of claims 107-108.

Claims 5 and 6 are drawn to a composition wherein antigens TbRa3 from *M. tuberculosis*, 38kD antigen from *M. tuberculosis*, Tb38-1 antigen from *M. tuberculosis*, and Fl TbH4 antigen from *M. tuberculosis* are linked forming a fusion polypeptide which has the amino acid sequence of TbF15.

Claims 107 and 108 are drawn to a fusion protein comprising a TbRa3 antigen from *M. tuberculosis*, 38kD antigen from *M. tuberculosis*, Tb38-1 antigen from *M. tuberculosis*, and Fl TbH4 antigen from *M. tuberculosis* wherein said fusion polypeptide has the amino acid sequence of TbF15.

12. Claims 8, 11 and 109, 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the difference between the set of claims 8, 11 and the set of claims 109, 111.

Claims 8 and 11 are drawn to a composition wherein antigens TbH9 from *M. tuberculosis* and HTCC#1 from *M. tuberculosis* are linked forming a fusion polypeptide which has the amino acid sequence of HTCC#1-TbH9.

Claims 109 and 111 are drawn to a fusion protein comprising a TbH9 antigen from *M. tuberculosis* and an HTCC#1 antigen from *M. tuberculosis* wherein said fusion polypeptide has the amino acid sequence of HTCC#1-TbH9.

13. Claims 13-14 and 112-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the difference between the set of claims 13-14 and the set of claims 112-113.

Claims 13 and 14 are drawn to a composition wherein SEQ ID NO:14(184-392) antigen from *M. tuberculosis*, a TbH9 antigen from *M. tuberculosis*, and a polypeptide comprising SEQ ID NO:14(1-129) from *M. tuberculosis* are linked forming a fusion polypeptide which has the amino acid sequence of SEQ ID NO:14(184-392)/TbH9/SEQ ID NO:14(1-129).

Claims 112 and 113 are drawn to a fusion protein comprising SEQ ID NO:14(184-392) antigen from *M. tuberculosis*, a TbH9 antigen from *M. tuberculosis*, and a polypeptide comprising SEQ ID NO:14(1-129) from *M. tuberculosis*, wherein said fusion polypeptide has the amino acid sequence of SEQ ID NO:14(184-392)/TbH9/SEQ ID NO:14(1-129).

14. Claims 16-17 and 114-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the difference between the set of claims 16-17 and the set of claims 114-115.

Claims 16-17 are drawn to a composition wherein antigens TbRa12 from *M. tuberculosis* and HTCC#1 from *M. tuberculosis* are linked forming a fusion polypeptide which has the amino acid sequence of TbRa12-HTCC#1.

Claims 114-115 are drawn to a fusion protein comprising a TbRa12 antigen from *M. tuberculosis* and an HTCC#1 antigen from *M. tuberculosis* wherein said fusion polypeptide has the amino acid sequence of TbRa12-HTCC#1.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 5 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,592,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a fusion protein comprising TbRa3, Tb38-1, TbH4 and 38kD antigens of *M. tuberculosis*. The fusion protein of instant claims 5 and 19 are listed only by name without any sequence information. Therefore, 5 and 19 encompass the same invention of claims 1-3 of U.S. Pat. No. 6,592,877.

Conclusion

17. Claims 2, 3, 5, 6, 8, 11, 13, 14, 16, 17, 19, 105-109, and 111-115 are rejected. Claim 11 is objected to for depending from a canceled claim. Claims 1, 4, 7, 12, 15, 18, and 20-27 are allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

August 31, 2004